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EMERGING TECHNOLOGIES AND DEVELOPING COUNTRIES: STEM CELL RESEARCH (AND CLONING) REGULATION AND ARGENTINA

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INTRODUCTION

Innovation is the mantra and arguably the engine of the modern, knowledge-based political-economy, and biotech innovation is one of the central pillars of the new 'innovation society'. Healthcare innovation – a key component of the biotech stream of innovation – is both an integral part of the innovation society and is reshaping that society, introducing new lexicons, redefining our understanding of desirable and undesirable bodily states, re-forging our relationships with our bodies, other people and the environment, and so on.¹ An important facet of healthcare innovation is stem cell research (SCR); research exploring the functions of or relying on stem cells (SCs). SCs are cells that divide asymmetrically; their division gives rise to an identical daughter cell (ie: thereby self-renewing) and to a differentiated cell (ie: one with a different and specialised function). Although different SCs exhibit different levels of plasticity depending on when they are harvested,² SCs no longer require proof of principle,³ and are generally accepted as a source of great potential for human welfare.

This paper explores the moral controversy surrounding human embryonic SCR (hESCR) and assesses its legal position in Argentina. An analysis of hESCR is important/timely because it is a much-hyped pursuit to which much hope is attached, and, simultaneously, a much-maligned pursuit to which much antipathy is directed. Frequently considered to be superior to adult SCR,⁴ hESCR is the site of mammoth

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¹ For insight into how SCR interacts with and influences culture, see C. Hauskeller. *Science in Touch: Functions of Biomedical Terminology*. *Bio & Phil* 2005; 20: 815-835. She concludes that biomedical science (its aims and developments) is so closely related to the cultural milieu and to social aims and development that the realms are inseparable.

² Totipotent SCs, harvested from the 8 cells of the zygote at approximately 36-hours post-fertilisation, can give rise to an entirely new organism, including the cells needed for human development. Pluripotent SCs, harvested when the inner cell mass of the blastocyst (ie: the mass which could otherwise form the embryo and evolve into the foetus) reaches approximately 25 cells, can differentiate into any and all of the 200+ cell types which comprise the human body, but cannot give rise to the extra-embryonic cells necessary to support the development of a foetus *in utero*. Multipotent SCs, harvested from the primordial germline cells of early aborted foetuses or from mature tissue (eg: from any post-foetal stage of life of the organism, including the late foetus, umbilical cord blood, children and adults), can give rise to the cell types regenerative of the tissue in which they normally reside.

³ A. Chapman et al. Report: Stem Cell Research and Applications: Monitoring Frontiers of Biomedical Research. 1999. Available at <http://www.aaas.org/spp/sfrr/projects/stem/report.pdf> [Accessed 2 Oct 2006].

⁴ See K. Devolder. Human Embryonic Stem Cell Research: Why the Discarded-Created-Distinction

bioethical clashes around unique issues relating to (1) the wellbeing of the embryo, the harvesting of which currently requires its destruction,⁵ and (2) the wellbeing of the collective, which is notionally threatened by certain processes associated with hESCR, most notably cloning, or 'somatic cell nuclear transfer' (SCNT⁶). An analysis of hESCR (and SCR more generally) in Argentina is important/timely because Argentina is a southern, economically fragile, developing country that is actively pursuing regenerative medicine and SC solutions to health problems. Indeed, Argentina is one of a handful of developing countries taking steps to build a competitive domestic market.⁷

Given the above, Part I examines the bioethical concerns raised by hESCR and attempts to articulate the moral values exposed by these concerns. Values are the underlying moral attitudes or foundation stones which tend to (1) justify the elevation of human life above other life, (2) elucidate the equality of all human life within the species, and (3) promote the wellbeing of and respect for persons. Here, values are understood as the deeply held and sometimes unarticulated ideals and principles which we as a society and as individuals hold, and which move societies/communities to respond, either positively or negatively, to possibilities.⁸ Part II shifts its consideration to the translation of these moral values (and ethical positions) into compelling action-guiding rules.⁹ It assesses how these underlying values have manifested (if at all) in regulatory instruments

Cannot be Based on the Potentiality Argument. *Bioethics* 2005; 19: 169-186, p. 169. For more on why researchers prefer ESCs, see R. Lovell-Badge. The Future of Stem Cell Research. *Nature*. 2001; 414: 88-91, and A. Newhart. The Intersection of Law and Medicine: The Case for Providing Federal Funding for Embryonic Stem Cell Research. *Vill Law Rev.* 2004; 49: 329-361. For a contrary view, see B. Capps. Bioethics and Misrepresentation in the Stem Cell Debate. 2005. Available at <http://www.ccels.cardiff.ac.uk/literature/publications/2005/capspaper.pdf> [Accessed 15 Mar 2006], L. Epatko. Adult Stem Cells: Conflicting Research. 2004. Available at <http://www.pbs.org/newshour/science/stem-cells/conflicting-research.html> [Accessed 3 Oct 2006], and M. Shambloot et al. Derivation of Pluripotent Stem Cells from Cultured Human Primordial Germ Cells. *NAS Proceedings*. 1998; 95: 13,726-13,731.

⁵ B. Salter & C. Salter. Bioethics and the Global Moral Economy: The Cultural Politics of Human Embryonic Stem Cell Science. 2006. Available at http://www.ioh.uea.ac.uk/biopolitics/publications/working_papers/wp3.pdf [Accessed 5 Oct 2006]. They state that hESCR generates cultural conflict not because its subject is SCs but because its subject is hESCs.

⁶ SCNT is a process whereby the nucleus of an adult cell is inserted into an enucleated egg, which is then induced to divide, thereby producing a blastocyst that is a genetic match to the adult cell/nucleus donor. For SCR purposes, the resulting cloned blastocyst is not permitted to develop into a full embryo; rather the pluripotent ESCs of the blastocyst are harvested and can then be used to treat the donor/patient without fear of immunological responses. This process is called therapeutic cloning, and is contrasted with reproductive cloning only in so far as its purpose rather than its technique is different. If the purpose of SCNT is human reproduction, the blastocyst would be implanted in a woman's uterus and permitted to grow into a baby. See Select Committee. 2002. *Stem Cell Research Report*. London: House of Lords. Available at <http://www.parliament.the-stationary-office.co.uk/pa/ld200102/ldselect/ldstem/83/8301.htm> [Accessed 26 Sep 2006].

⁷ H. Greenwood et al. Regenerative Medicine: New Opportunities for Developing Countries. *Int J Biotech*. 2006; 8: 60-76; K. Thorn. World Bank Working Paper: Science, Technology and Innovation in Argentina: A Profile of Issues and Practices. 2005. Available at <http://siteresources.worldbank.org/intargentina/resources/sciencetechnologyandinnovationinargentina.pdf> [Accessed 3 Oct 2006].

⁸ For more on values, see S. Harmon. Regulation of Human Genetics and Genetic Biotechnology: Risks, Values and Analytical Criteria. *InnoGen WP-40*. 2005. Available at http://www.innogen.ac.uk/assets_innogen/dynamic/1132844739842/Innogen-Working-Paper-40.pdf; A. Bruce & J. Tait. Interests, Values and Biotechnological Risk. *InnoGen WP-7*. 2003. Available at http://www.innogen.ac.uk/assets_innogen/dynamic/1118847372616/Innogen-Working-Paper-7.pdf.

⁹ For more on the translation of values into binding rules, see S. Harmon. *Ibid.*; K. Henley. Abstract Principles, Mid-Level Principles and the Rule of Law. *Law & Phil.* 1993; 12: 121-132; M. Bayles. Moral Theory and Application. *Soc Theo & Pract.* 1984; 10: 110-114.

relevant to hESCR in Argentina. The paper concludes with an assessment of the adequacy of Argentina's regulation and some suggestions for moving forward.

ETHICAL DEBATES AND MORAL VALUES UNDERPINNING hESCR

Positions on the use of the embryo turn on an assessment of three overlapping questions relating to the (pre)individual (eg: When does human life begin? What is the moral status of the embryo? What is the meaning of personhood?), and a balancing of our conflicting obligations relating to the collective (ie: our obligation to take action intended to alleviate the social damage caused by serious injury and debilitating disease, on the one hand, and, on the other, to avoid the potential social damage caused by the outputs of those actions). Assessments have resulted in the development of at least four divergent (ethical) positions.

Prohibitive Position

This position holds that human life and personhood occur simultaneously at the moment of conception, and the embryo's unique potential to develop into a complex organism substantially different from any other known entity endows it with a right to special protection.¹⁰ Thus, it is immoral to take any action which prevents the embryo from fulfilling its potential. Emphasising the risks over the (potential) benefits of hESCR, it expresses concern over instrumentalisation and questions the morality of a society (and the position of individuals within it) which routinely destroys early human life for inquisitive purposes. A component of this argument is the claim that hESCR is too closely tied to SCNT; advances in therapeutic SCNT (intended to increase the number of SCs available and to eventually overcome immunological responses in patients), eliminate important obstacles to the acceptability of reproductive SCNT (eg: lack of safety¹¹) with the result that hESCR constitutes a slippery slope to the eventual (inevitable) application of SCNT as a means of reproduction, which raises a host of social woes.¹² As such, proponents would prohibit procuring or using hESCs, or indeed

¹⁰ See J. Deckers. Why Current UK Legislation on Embryo Research is Immoral: How the Argument from Lack of Qualities and the Argument from Potentiality Have Been Applied and Why They Should be Rejected. *Bioethics*. 2005; 19: 251-271; Pontifical Academy for Life. Declaration on the Production and the Scientific and Therapeutic Use of Human Embryonic Stem Cells. 2000. Available at http://www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pa_acdlife_doc_20000824_cellule-staminali_en.html [Accessed 18 Oct 2006]; R. Doerflinger. Destructive Stem-Cell Research on Human Embryos. *Origins*. 1999; 28: 769-773.

¹¹ Currently, SCNT is inefficient and, for reproductive purposes, both ineffective and unsafe: see the survey of scientific opinions in G. Annas & S. Elias. Politics, Morals and Embryos. *Nature*. 2004; 431: 19-20, at fn 13 and 90. As such, there is an international consensus to the effect that it is unethical: see Article 11 of UNESCO's Universal Declaration on the Human Genome and Human Rights (1997), Article 1 of the Council of Europe's Additional Protocol on Cloning Protocol (1998), and others. See also R. Chester. Cloning Embryos from Adult Human Beings: The Relative Merits of Reproductive, Research and Therapeutic Uses. *New Eng LR*. 2005; 39: 583-607. It has been postulated, however, that once our understanding increases such that reproductive SCNT is safe, the prevailing consensus may disintegrate: R. Brownword. Stem Cells and Cloning: Where the Regulatory Consensus Fails. *New Eng LR*. 2005; 39: 535-571.

¹² It is claimed that reproductive cloning would: cause emotional and psychological suffering in clones due to a lack of sense of independent self; infringe the clone's autonomy through parental selection practices which impose characteristics that circumscribe their ability to experience an 'open future'; compromise the clone's dignity due to the 'unnatural' intervention in the reproductive process that spawned him/her; create confusion and ambiguity around familial relationships; alter the culture of reproduction such that children would be seen as commodities with characteristics to be bartered and selected; encourage

conducting embryonic research, for any purpose other than assisting reproduction.

This position relies on two overarching core values. The first, 'human dignity', generally encapsulates the idea that individuals must be afforded honour and respect, and that the human species has a unique value which must be maintained through enhanced protection.¹³ A violation of dignity occurs whenever an act directed toward another is viewed, on an *objective* basis, as humiliating, insulting, shameful, contemptuous or damaging to the whole of humanity. In this respect, dignity is deployed as a *constraining mechanism*, with its limits determined by some authority and imposed on everyone. The second value, 'sanctity of life', generally connotes an aversion to harm and an elevation of human life above all other forms of life.¹⁴ In a similarly dogmatic vein, sanctity is interpreted such that human life is deemed intrinsically valuable/sacred and deserving of priority over all other considerations, including comfort, health, actualisation, and the advancement of knowledge.

Restrictive Position

Proponents of this position adopt comparable stances on the commencement of human life and personhood and similar interpretations of dignity and sanctity, which values figure prominently in their ethical judgment. However, they marshal these in support of a less strict (and less consistent) approach to using hESCs. They would prohibit procuring hESCs, but would allow research to continue on those cell lines already in existence, viewing the unethical damage to have already been done.¹⁵

Permissive Position

Proponents of this position believe that, though genetically human, the embryo has none of the necessary characteristics of personhood (eg: uniqueness, sentience, and the cognitive capabilities of consciousness, reasoning and self-awareness).¹⁶ Drawing

a culture of market and consumption around children (made worse by inevitable disreputable cloners and consumers); and encourage eugenic selection processes and discriminatory attitudes based on new categories. In short, children would be either 'damaged goods' or 'finished goods', but they would be 'goods' in the instrumental meaning of the word. Families would be confusing morasses with greater potential for exploitation, and society would become more discriminatorily balkanised with negative knock-on effects for justice. See B. Taylor. *Whose Baby Is It? The Impact of Reproductive Technologies on Kinship*. *Hum Fert*. 2000; 8: 189-195; R. Santorum. *The New Culture of Life: Promoting Responsible and Appropriate Medical Research*. *Notre Dame JLEPP*. 2003; 17: 151-156; C. Sunstein. *Is There a Constitutional Right to Clone?* *Hastings LJ*. 2002; 53: 987-1005; L. Andrews. *Is There a Right to Clone? Constitutional Challenges to Bans on Human Cloning*. *Harv J Law & Tech*. 1998; 11: 643-681; L. Wu. *Family Planning Through Human Cloning: Is There a Fundamental Right?* *Col LR*. 1998; 98: 1461-1515; D. Davis. *Genetic Dilemmas and the Child's Right to an Open Future*. *Rutgers LJ*. 1997; 28: 551-592.

¹³ M. Cutter. 2004. Genetic Databases and What the Rat Won't Do: What is Dignity at Law? In *Blood and Data: Ethical, Legal and Social Aspects of Human Genetic Databases*. G. Arnason et al., eds. Reykjavik: UIP: 217-222, p. 219.

¹⁴ P. Suber. *Against the Sanctity of Life*. 1996. Available at <http://www.earlham.edu/~peters/writing/sanctity.htm> [Accessed 5 Aug 2005].

¹⁵ The US federal funding policy of supporting research on SC lines created before 2001, but not permitting the creation of new lines represents such a bifurcated approach, which, coincidentally, leaves private sector conduct unregulated, and has been described as ethically inconsistent: see BBC, Bush 'Out of Touch' on Stem Cells. 2006. Available at <http://news.bbc.co.uk/2/hi/science/nature/5197926.stm> [Accessed 18 Oct 2006]. For US opinion polls on SCR, see <http://www.pollingreport.com/science.htm>.

¹⁶ For an interesting discussion on the status of the embryo, see H. McLachlan. *Persons and Their Bodies: How We Should Think About Human Embryos*. *Health Care Analysis*. 2002; 10: 155-164.

support from religion, biology, and law,¹⁷ they argue that, although embryos are deserving of some ‘moral awe’,¹⁸ they are not sacrosanct. As such, using embryos left over from IVF treatment for virtuous ends is more consonant with attributing moral status to them than is destroying them.¹⁹ By utilising existing embryos before they are in a position to ‘experience’ loss, this position affords them moral status (greater than if those embryos were simply discarded). They stipulate, however, that embryos must never be *created* for the sole purpose of destruction/research; to do so would be to legally create an underclass of beings with a purely instrumental role in society.²⁰

Like those above, permissive proponents rely on dignity and sanctity. However, dignity is viewed as an *empowering* value. Espousing a *subjective* interpretation, proponents perceive a violation of dignity whenever an act is perpetrated against another which *that other* considers humiliating, insulting, contemptuous or damaging (ie: its breach depends on the individual’s sensibilities).²¹ Sanctity refers not to the un-utilisable sacredness of life, but to the uniqueness of the *lived* human experience (beyond mere biological existence), thereby taking into account other life interests (eg: health, comfort, social interaction).²² These interpretations implicate another core value: ‘autonomy’, which encompasses physical and psychological liberty and the right to be free from coercion within the reasonable limitations imposed by cherished relationships (eg: familial or community).²³ Thus, proponents afford respect to individuals by recognising their autonomous right to make moral judgments (about their embryo and research) and their moral agency around donation.

Facilitative Position

This position views the embryo as nothing more than a collection of cells like that of other bodily tissue. Demanding consistency, proponents argue that, if it is morally acceptable to create embryos to help the infertile (or to conduct pre-implantation genetic diagnoses), it can be no less moral to create them to help the ill or injured (or for research that will benefit the ill/injured). Moreover, the most ethically and practically defensible

¹⁷ See H. Greely. Moving Human Embryonic Stem Cells from Legislature to Lab: Remaining Legal and Ethical Questions. *PLOS Medicine*. 2006; 3: e143; C. Dabu. Stem-Cell Science Stirs Debate in Muslim World Too. 2005. Available at <http://www.csmonitor.com/2005/0622/p15s02-wogi.html> [Accessed 29 Sep 2006]; L. Cahill. The Embryo and the Fetus: New Moral Contexts. *Theo Studies*. 1993; 54: 124-142.

¹⁸ A term used by A. McCall-Smith & M. Revel (Rapporteurs). 2001. *Report to the IBC: The Use of Embryonic Stem Cells in Therapeutic Research*. Paris: UNESCO. Available at http://portal.unesco.org/shs/en/file_download.php/64b74abda57372bdc22570b42c1718f1stemcells_en.pdf [Accessed 5 Oct 2006].

¹⁹ R. Isasi & B. Knoppers. Beyond the Permissibility of Embryonic and Stem Cell Research: Substantive Requirements and Procedural Safeguards. *Hum Reproduction*. 2006; 21: 2474-2481, p. 2477.

²⁰ W. Cheshire Jr. Small Things Considered: The Ethical Significance of Human Embryonic Stem Cell Research. *New Eng LR*. 2005; 39: 573-582.

²¹ For more on this, see D. Statman. Human Dignity and Technology. 2004. In Arnason et al., *op. cit.* note 13, p. 223-228; A. Capron. Indignities, Respect for Persons, and the Vagueness of Human Dignity. 2003. Available at <http://bmjournals.com/cgi/eletters/327/7429/1419#44060> [Accessed 2 Aug 2005]; D. Beylerveld & R. Brownsword. 2001. *Human Dignity in Bioethics and Biolaw*. Oxford: OUP.

²² K. Boyd. Medical Ethics: Principles, Persons, and Perspectives: From Controversy to Conversation. *J Med Ethics*. 2005; 31: 481-486.

²³ Harmon, *op. cit.* note 8; R. Scott. 2002. *Rights, Duties and the Body*. Oxford: Hart Publishing; S. Aksoy & A. Elmali. The Core Concepts of the ‘Four Principles’ of Bioethics as Found in Islamic Tradition. *Med Law*. 2002; 21: 211-224; T. Beauchamp & J. Childress. 1994. *Principles of Biomedical Ethics*, 4th ed. Oxford: OUP. R. Gillon. Ethics Needs Principles - Four Can Encompass the Rest - and Respect for Autonomy Should be ‘First Among Equals’. *J Med Ethics*. 2003; 29: 307-312, argues that autonomy must be respected if morality is to exist.

position for a diverse, pluralistic society, they claim, is one which affords individuals, and therefore society, options. Society must not be held hostage to the restrictive beliefs of a minority.²⁴ Rather, our obligation to do everything possible to alleviate the suffering of existing and future human beings must be approached robustly; intergenerational justice demands that we enhance the life chances of emerging and future generations.²⁵ Positive action must be undertaken even where such action incurs costs and/or creates risks. If hESCR has the potential to achieve this social end, then, despite its costs, there is a moral duty to pursue it and the limitations imposed on its pursuit must be minimal and narrow.²⁶ Given the above, proponents of this position view (1) the use of embryos surplus from IVF, and (2) the *creation* of embryos for research purposes either through IVF-facilitated gestation or through SCNT as acceptable. That is not to say that every use is acceptable; frivolous uses (eg: for the creation of cosmetics or for use in animal feed) diminish the moral respect shown to the embryo and are unacceptable. But generally, conducting controversial research in the absence of knowledge about its ultimate social impact is acceptable and must be permitted because such research *may* prove beneficial to society.²⁷

Proponents attach great importance to autonomy, giving full credit to the individual's right to make choices and take actions based on personal beliefs; indeed, they insist that the state must *enable* individuals to do so.²⁸ As such, donors must be empowered to gestate and offer embryos for research and the betterment of humanity. Similarly, researchers must be given latitude in exercising their moral right to pursue scientific knowledge.²⁹ The value of 'solidarity' is also implicated. Solidarity recognises that individuals are naturally and irrevocably embedded in social contexts and thus have a duty – grounded in compassion, fraternity, interest in human welfare, and a desire to construct a just and decent society where everyone's life chances are supported – to undertake personal and collective actions to promote the welfare of individuals and society; enhancing the health and quality of life of living and future humans is imperative.³⁰ Although autonomy and solidarity often in conflict, this position ties them together through its claim that the moral life requires *positive action* in response to identified, response-demanding human needs, and that individuals must therefore be

²⁴ K. Devolder. What's in a Name? Embryos, Entities and ANTities in the Stem Cell Debate. *J Med Ethics*. 2006; 32: 43-48; J. Childress. An Ethical Defence of Federal Funding for Human Embryonic Stem Cell Research. *Yale JHPLE*. 2001; 2: 157-165.

²⁵ It is a curious juxtaposition that sees proponents of this position invoking the wellbeing of future individuals to justify use of embryos to which they attach no significant moral value.

²⁶ O. Corrigan et al. Ethical, Legal and Social Issues in Stem Cell Research and Therapy. 2005. Available at http://www.eescn.org.uk/pdfs/elsi_paper.pdf [Accessed 3 Oct 2006], p. 6.

²⁷ J. Shaw. Stem Cell Science: When Medicine Meets Moral Philosophy. 2004. Available at <http://www.harvardmagazine.com/on-line/070483.html> [Accessed 29 Sep 2006], quotes Prof. R. Losick making a similar argument in the context of the academic world (ie: universities have a responsibility to support controversial basic research on the understanding that it may or may not be beneficial to the world).

²⁸ Beauchamp & Childress, *op. cit.* note 23, p. 125.

²⁹ A right that is well established at international law: see provisions in the Universal Declaration of Human Rights (1948), the International Covenant of Social and Cultural Rights (1966), the Universal Declaration of the Human Genome and Human Rights (1997), and the Preliminary Draft Declaration on Universal Norms on Bioethics (2005).

³⁰ S. Harmon. Solidarity: A (New) Ethic for Global Health Policy. *Health Care Analysis*. 2006; 14: 215-236. See also S. Benatar, A. Daar & P. Singer. Global Health Ethics: The Rationale for Mutual Caring. *Int Aff*. 2003; 79: 107-138; R. Houtepen & R. ter Meulen. The Expectation(s) of Solidarity: Matters of Justice, Responsibility and Identity in the Reconstruction of the Health Care System. *Health Care Analysis*. 2000; 8: 355-376; R. ter Meulen et al. Final Report: Solidarity and Care in the European Union. 2000. Available at http://europa.eu.int/comm/research/biosociety/pdf/bmh4_ct8_3971_partb.pdf [Accessed 24 Aug 2005].

empowered to undertake that positive action. The fact that new ideas and technologies create controversy and resistance (because they challenge existing thinking, boundaries and visions of the world) is of little consequence.

Summation: legitimate plurality and enduring controversy

Although the motivating interests of the proponents of the competing positions have not been investigated, it is clear that each position is grounded in fundamental moral values aimed at promoting a just and moral society. Moreover, and perhaps ironically given the irreconcilability of these positions, they are grounded in a relatively *small* pool of moral values, which values have been interpreted in conflicting though not necessarily unreasonable ways. The resultant moral plurality bears out a claim articulated by Rawls that irresolvable comprehensive conceptions of the good lie within the limits of reason, thereby constraining our capacity for agreement.³¹ The moral foundation of the present plurality – a plurality symptomatic of a globally communicative modern society that has become subjective and individualistic³² – has disinclined proponents of one position from conceding to the others' positions. In short, a consensus on the acceptability and scope of hESCR has been and will remain elusive, even within relatively small juridical boundaries.³³

So what is to be done? In a democratic setting, with institutions geared toward enabling personal freedom and plurality, we might rely on the personal morality of actors within the field. Indeed, such an approach would likely suit certain actors. However, in a deeply divisive field like hESCR – which, in addition to morality, implicates commerce and development, technology and innovation, public and private actors, and individual and public health, present and future – stakeholders might rightly claim that public, not private, morality is important, and they may reasonably demand that actors be bound by something more than personal judgments based on individually-held values – something more coercive. The most appropriate and effective form of coercive boundary-setting is legislated regulation:

[Given that] ... pluralism makes it impossible to presuppose a system of norms of correct behaviour which can be comprehended by everyone and accepted by all members of society ... positive law ... must serve the social order ... and be strong enough to end the struggle of convictions and competing interests.³⁴

³¹ See J. Rawls. 1993. *Political Liberalism*. NY: Columbia U. Press; and the comments on same in A. van de Putte. Rawls' Political Liberalism: Foundations and Principles. *Ethical Perspectives*. 1995; 2: 107-129; J. Rawls. The Idea of Public Reason Revisited. *U Chi Law Rev.* 1997; 64: 765-807; O. O'Neill. Political Liberalism and Public Reason: A Critical Notice of John Rawls' Political Liberalism. *Phil Rev.* 1997; 106: 411-428.

³² H. Sandkühler. Pluralism and the Universality of Rights. 1998. Available at <http://www.bu.edu/wcp/papers/law/lawsand.htm> [Accessed 9 Mar 2007].

³³ McCall-Smith & Revel, *op. cit.* note 18, state that status or personhood arguments have been prolonged and marked by utter failure to reach agreement. Lack of consensus is exemplified at the international level by the prolonged attempt to realise an international declaration on cloning technology and the politics surrounding its eventual failure in February 2005: see UN, Press Release: Legal Committee Recommends UN Declaration on Human Cloning to General Assembly: UN Doc. GA/L/3271, February 18, 2006. Available at <http://www.un.org/news/press/docs/2005/ga13271.doc.htm> [Accessed 10 Oct 2006]. See also L. Walters. Human Embryonic Stem Cell Research: An Intercultural Perspective. *Ken Inst Ethics J.* 2004; 14: 3-38.

³⁴ Sandkühler, *op. cit.* note 32.

However, it has been suggested that excessive legal coercion with inadequate common deliberation and discussion causes democratic societies to perish.³⁵ The answer to such concerns is deliberative democracy, which, through multiple engagement mechanisms, requires stakeholders to justify their demands for collective action by giving (and debating) reasons that can be accepted by those ultimately bound by decisions. Indeed, it is said that deliberative democracy (1) promotes openness and fairness, and minimise strategic manipulation, (2) promotes respectful decision-making in morally conflictual settings, (3) reduces the chance and consequences of acting with incomplete understanding, (4) promotes legitimacy in the face of decisions surrounding scarce resources, and (5) encourages solidaristic perspectives on public issues.³⁶ Though deliberative exercises may never achieve consensus around the scope of hESCR (because of the well-articulated, entrenched plurality outlined above), and therefore derivative statutory regulation may not represent public articulation of *universally* accepted behavioural norms, where outputs clearly draw on widely held values openly debated, deliberative democracy-spawned regulation is valid and plays an important role in the construction of a just and moral society.³⁷ Indeed, only through the use of deliberative democracy (public engagement) can we be reasonably confident that (1) all interested stakeholders have participated, (2) all actors have adequate notice of socially acceptable conduct, and (3) all actors are subject to the same mechanisms for enforcing that conduct, all of which are morally defensible elements of a pluralistic democracy. There is obviously a risk that such an exercise will result in a regime that restricts conduct and therefore thwarts research, but that is a matter for (further) social/political negotiation.

REGULATION AND CONTROL OF hESCR IN ARGENTINA

Argentina has *not* enacted any law which explicitly governs hESCR, or the related fields of IVF or embryonic research, nor even articulated much in the way of public policy on same.³⁸ Indeed, the only statutory instrument potentially relevant to hESCR is the Prohibition on Human Cloning Research (1997 Decree),³⁹ which, it must be conceded, is silent on matters relevant to SCR except insofar as cloning is closely associated with hESCR. Thus, although the 1997 Decree is directed at cloning, and therefore only tangentially impacts on hESCR, and although it was not arrived at deliberatively after public debate, it will nonetheless be the subject of the remainder of the analysis, which will assess its content in relation to the (pre)individual and the collective, both of which are, as demonstrated above, the subject of moral concern.

³⁵ J. Bohman. Public Reason and Cultural Pluralism: Political Liberalism and the Problem of Moral Conflict. *Pol Theory*. 1995; 23: 253-279.

³⁶ P. Hamlett. Technology Theory and Deliberative Democracy. *Sci Tech & Human Values*. 2003; 28: 112-140; A. Gutmann & D. Thompson. Deliberating About Bioethics. *Hastings Centre Report* 27. 1997; 3: 38-41. For more on deliberative democracy, see A. Gutmann & D. Thompson. 1997. *Democracy and Disagreement*. Boston, MA: HUP; E. Charney. Political liberalism, Deliberative Democracy and the Public Sphere. *Am Pol Sci Rev*. 1998; 92: 97-110; J. Dryzek & C. List. Social Choice Theory and Deliberative Democracy: A Reconciliation. *Brit J Pol Science*. 2003; 33: 1-28; J. Dryzek Deliberative Democracy in Divided Societies: Alternatives to Agonism and Analgesia. *Pol Theory*. 2005; 33: 218-242.

³⁷ And the law must be seen as ethically sound if it is to operate effectively (ie: be observed by its target population): Capps, *op. cit.* note 4.

³⁸ Isasi & Knoppers, *op. cit.* note 19, p. 2475. F. Arzuaga, e-correspondence dated October 30, 2006, indicates that there have been no official government position papers or reports on SCR to date, though the Science & Technology Promotion Agency created an Advisory Commission on Stem Cells in October 2006, which Commission has not yet produced its opinion.

³⁹ Presidential Decree No. 200/1997.

Legal protections for the (pre)individual

The only substantive provision of the 1997 Decree is Article 1, which states that ‘all cloning experiments relating to human beings are prohibited’.⁴⁰ Assessed in its own right (as an explicit prohibition of a specified, though not well-defined scientific activity), its intent is self-evident and one can reasonably assume that its motivating ethical position is the restrictive position with its concomitant underlying values. Reference to its Recitals only adds minimally to our understanding of Argentina’s position. For example:

- Recital 1 states, *inter alia*, that it is the inviolable duty of the state to defend the dignity of the human being.⁴¹ Although it fails to define its interpretation of human dignity, the 1997 Decree deploys it in the constraining sense. One can therefore assume that the legislators felt cloning would diminish human dignity in some way, though it is wildly speculative to offer any insight as to how they may have thought it did so.
- Recital 3 states that scientific advances in the public domain have resulted in human cloning research being possible, thereby creating ethical and moral problems that run contrary to the values and customs of the people.⁴² This is further reference to a moral foundation, but there is no reference to the specifics of the ethical/moral problems envisioned, nor, more importantly, aside from the previous bland reference to dignity, is there any articulation of what the “values and customs” of the people might be and how they impact on the individual.
- Recital 6 states that the government has taken account of the opinions of different religious groups and scientific institutions, and the positions of different countries that have adopted a view on the subject.⁴³ However, it gives no hint as to which groups/institutions/states it considered or found compelling, and so, again, one is left in the dark as to the precise moral foundation of the prohibition.

Given the above, although there are gigantic gaps in the teachings discernable from the 1997 Decree’s very curt and minimalist text, it can be inferred that constraining and restrictive interpretations of dignity and sanctity are operative. Somehow cloning diminishes the dignity of the individual and it must therefore be prohibited. From this we can infer that, to the extent that the prohibition is motivated by a desire to protect the individual at all, it effectively translates these motivating values into legal rules (ie: constraint is the order of the day).

But what might this position on cloning say about Argentina’s position on hESCR, and, more particularly, the position of the embryo (pre-individual) and donor

⁴⁰ Article 1 states, “El Presidente de la Nación Argentina en Acuerdo General de Ministros Decreta: Prohíbense los experimentos de clonación relacionados con seres humanos”. The remaining 3 provisions of the 1997 Decree merely direct further action and stipulate that the 1997 Decree is to be inscribed as the law of the land.

⁴¹ Recital 1 states, “Que es función indelegable del Estado la defensa de la dignidad de la persona humana, la preservación de su salud y la calidad de vida de los habitantes”.

⁴² Recital 3 states, “Que los avances científicos que son de conocimiento público posibilitan la realización de experimentos de clonación humana que plantean problemas éticos y morales que se contraponen a las pautas y valores culturales propios de nuestro pueblo”.

⁴³ Recital 6 states, “Que, igualmente, ha tomado conocimiento de las opiniones formuladas por representantes de distintos credos religiosos e instituciones científicas y de las decisiones adoptadas por gobiernos de diversos países fijando posiciones concretas al respecto”.

(individual), and are the values identified consistently realised? One can infer from the text and tenor of the instrument that Argentina's approach to hESCR may be similarly restrictive. If research involving therapeutic cloning infringes or is an affront to the dignity and sanctity of the individual, then, to be consistent, Argentina should adopt a prohibitive or restrictive position on hESCR, or at least offer some protection for the dignity and sanctity of the embryo and the individual in the hESCR.

However, there is no legal protection (of the dignity and sanctity) of the embryo or (of the dignity and autonomy) of the individual participant/donor in either the 1997 Decree or in any other enforceable regulatory instrument.⁴⁴ The practical consequences of this carving out of cloning for particular attention, combined with silence on other issues, would seem to be that both the use of surplus IVF embryos and the gestation of embryos for obtaining hESCs for research is permitted. Similarly, given the legislative silence on the issue of international collaborations and the importation of SC lines, it would seem that both (1) the importation and use of SC lines derived from surplus embryos, and (2) the importation and use of SC lines derived from therapeutic cloning, is also permitted.

In light of this apparent permissiveness, which seems out of step with the 1997 Decree, one would hope for some guidance – either in the 1997 Decree or some related instrument (given Recital 4, which specifies the need to regulate practices associated with cloning and human experimentation⁴⁵) – regarding Argentina's position on:

- the status of the embryo and a definition of same;⁴⁶
- when (or whether) the embryo can be used to derive SCs for research purposes;
- the status of and protections for individuals participating in SCR and/or the related fields of IVF or human subject research more generally.

However, none is offered and, presumably, limits on personal actions are left to non-governmental instruments or personal morality/conscience.

Legal protections for the collective

As suggested above, cloning is a particularly important site for considerations of collective wellbeing, and issues relating to collective wellbeing require balancing actions and restrictions with a view to promoting a moral and just society. In the present context, and to grossly oversimplify the problem, a balance must be struck between permissive, human rights-based, and solidarity- and autonomy-inspired scientific freedom, on the one hand, and restrictive, risk-based, and dignity- and sanctity-inspired limitations, on the other hand. Does the instrument offer guidance on and (moral) justification for the balance it has struck via its operative provisions?

⁴⁴ L. Baranao, President, National Agency for the Promotion of Science & Technology, representations made at informal meeting in Edinburgh on October 26, 2006. The Argentine Ministry of Health has commenced work on human subject research guidelines, but no results have yet been published: F. Arzuaga, *supra*, note 40.

⁴⁵ Recital 4 states, "Que, por ello, resulta de urgente necesidad reglamentar, controlar y fiscalizar todas las actividades relacionadas con los experimentos de clonación, en particular con seres humanos".

⁴⁶ The importance of such a definition and its absence in Argentina is noted in R. Isasi et al. Legal and Ethical Approaches to Stem Cell and Cloning Research: A Comparative Analysis of Policies in Latin America, Asia and Africa. *J Law Med. & Ethics*. 2004; 32: 626-638.

The 1997 Decree does, by virtue of its explicit prohibition of cloning in Article 1, offer some (minimal) guidance on the balance deemed appropriate for Argentina with respect to the scope of health research. Unfortunately, little can be said about the underlying values by which the state is being compelled to engage in this limits-setting exercise, although the same assumptions as made above likely apply. Recital 3 hints at a moral awareness and Recital 1 references human dignity (now collectively understood as serving to promote the dignity of society as a whole). It could be argued that this limitation sits uneasily with the recognition, also in Recital 1, of the state's duty to preserve the health and quality of life of its citizens, a claim that seems to implicate the solidarity value.

Ultimately, by virtue of the 1997 Decree, Argentina has implied that morally grounded health research is considered important, but that health research which implicates human cloning cannot, for some reason which is not made clear, be considered moral, and therefore cannot be pursued.

Summation: a moral/legal disconnect

Through the 1997 Decree, Argentina has attempted to regulate not hESCR but rather one scientific process (cloning) associated with hESCR (and particularly important to issues relating to collective wellbeing). As such, it is conceded that evaluations of the 1997 Decree as a regulatory instrument for hESCR may be unfair, but those above (and the conclusions below) are warranted insofar as they comment on (1) the general worth of the instrument, and (2) its potential impact on hESCR, in whose orbit it obviously spins.

With respect to the worth of the 1997 Decree in its own right as a regulator of research relying on cloning techniques, this minimalist instrument exhibits some terrific shortcomings, most particularly related to its potential efficacy. It contains no provision for monitoring activities or enforcing compliance with its prohibition (or for furthering moral values embodied in its prohibition, which are, in any event, left undefined). Further, the 1997 Decree directs the Ministry of Health and Social Action to write a bill related to this matter (cloning and associated practices?) within 60 days.⁴⁷ However, there has been no follow-up regulation addressing these matters or otherwise offering guidance relating to hESCR.

With respect to the second point – the 1997 Decree's impact on hESCR – when measured against its own disclosed awareness of regulatory need in this area, its utility is little better. For example, Recital 2 stipulates the need to 'ensure and guarantee' the correct utilisation of techniques and procedures applicable to human beings.⁴⁸ Similarly, Recital 4 notes 'the urgent need to regulate and control all activities *associated with* cloning, especially experiments involving human beings'.⁴⁹ However, its application is limited to cloning and it ignores hESCR, inarguably a procedure/technique both 'associated with' cloning and 'applicable to' human beings. And again, as noted above, no further regulation addressing these matters has been adopted.

On balance, Argentina's attempt at regulation could be characterised as morally incoherent, socially inadequate, and, in light of the importance of deliberative democracy noted above, democratically deficient:

⁴⁷ Article 2 states, "Encomiéndase al Ministerio de Salud y Accion Social que, en un plazo no mayor de Sesenta (60) días, elabore el proyecto de ley respectivo".

⁴⁸ Recital 2, which states, "Que, asimismo, el Estado debe asegurar y garanatizar el correcto empleo de los procedimientos y técnicas de uso y aplicación en los seres humanos".

⁴⁹ Recital 4.

- Morally Incoherent: Argentina's approach exposes an apparent disconnect between the broad, fundamental values (apparently) held by Argentine society and the official legal position which obtains (with respect to hESCR). With respect to its value-position, Argentina has: (1) ratified the American Convention on Human Rights (1969),⁵⁰ which states that every person has the right to have his life protected by law from the moment of conception;⁵¹ and (2) constitutionally entrenched catholic dogma,⁵² which views the creation of embryos for research purposes as the creation of 'sacrificial victims predestined to be immolated on the altar of scientific progress'.⁵³ Thus, although Argentina's legal and constitutional character and conservative social history suggest that it should hold the 'restrictive position' outlined in Part I, the regulatory status of hESCR does not reflect these positions. The regulatory position is that only the performance of SCNT for deriving (1) hESCs for research, or (2) embryos for reproduction, is forbidden. One might claim that autonomy (manifesting respect for others by allowing them to make decisions for themselves) is exposed by this state of affairs. Researchers (and companies) are permitted to pursue their work largely unfettered by regulatory limitations or oversight, and one can only hope that they will work toward ends that are socially useful. However, one can contest this proposition, arguing that the researcher liberty which apparently prevails does not 'promote' autonomy; it does not create space/opportunity to do a particular thing or range of things. It is therefore stretching the inference to claim that inactivity can masquerade as respect for autonomy.
- Socially Inadequate: A number of circumstances which obtain in Argentina make the unregulated and unsupervised advancement of SCR potentially dangerous. First, although some treatments have been administered for years (eg: bone marrow transplants for leukaemia patients⁵⁴) and research is advancing apace (eg: SCs are being used to examine protein, gene and cancer functions and to promote healing in neural fibres⁵⁵), fundamental hurdles remain to our understanding of how SCs work inside and outside the body (eg: SC lines are difficult to maintain, have yet to efficiently produced large quantities of cells, and experience random differentiation and genetic instability, and the movement and behaviour of SCs

⁵⁰ American Convention on Human Rights, 1969, OAS Treaty Series, No. 36.

⁵¹ Ibid: Article 4.

⁵² See s. 2, Argentinean Constitution 1853. Available at http://www.oefre.unibe.ch/law/icl/ar00000_.html, which obliges the federal government to 'support the Roman Catholic Apostolic religion'.

⁵³ Pontifical Academy for Life. The Dignity of Human Procreation and Reproductive Technologies: Anthropological and Ethical Aspects. 2004. Available at http://www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pont-acd_life_doc_20040316_x-gen-assembly-final_en.html [Accessed 31 Oct 2006]. Indeed, it has been noted that Latin American legislators receive mandates from the Vatican and frequently act under Vatican morality rather than exercise their own free choice: F. Zegers-Hochschild. Attitudes Towards Reproduction in Latin America: Teachings from the Use of Modern Reproductive Technologies. *Hum Reproduction Update*. 1999; 5: 21-25. This deference to the church goes so far as to criminalising abortion in all circumstances and refraining from legislating on IVF: see E. Rivera-Lopez. Ethics and Genetics in Latin America. *Developing World Bioethics*. 2002; 2: 11-20.

⁵⁴ Chapman et al., *op. cit.* note 3.

⁵⁵ Devolder, *op. cit.* note 4; Corrigan et al., *op. cit.* note 26; E. Singer. Stem Cell Mix Helps Paralyzed Rats Walk. 2006. Available at http://www.technologyreview.com/printer_friendly_article.aspx?id=17029 [Accessed 29 Sep 2006]; S. Kadereit & P. Hines. An Overview of Stem Cell Research. *New Eng LR*. 2005; 39: 607-622, p. 613.

introduced into a natural environment cannot yet be predicted⁵⁶). Second, the usual shackles of developing country innovation (eg: underdeveloped technical, financial and legal capacity) are only partially present in Argentina, which has already taken many positive steps to build its SCR capacity and is now advanced in its health research and SCR activities. With respect to the former, although its overall R&D spending is relatively low by international standards (ie: in 2004, R&D spending represented 0.44% of GDP, and of that, 14% related to health research), Argentina is one of the top 25 most productive research countries and is listed as a world player in SCR spending.⁵⁷ With respect to treatments, adult SC-based cerebral infarction treatments and diabetic insulin production treatments have been administered to patients,⁵⁸ and multi-centre international SC collaborations are being pursued with respect to congestive heart failure.⁵⁹ Third, biotechnology (and SCR) represents an opportunity for developing countries like Argentina to build capacity alongside developed countries, thereby blurring the developed/developing divide (ie: it represents a ‘leapfrog’ technology similar to mobile phones).⁶⁰ For this to occur and for maximum benefit to be realised, an innovation-friendly environment must be fostered. Such an environment does not entail abdication of moral limits or public oversight, but is characterised by regulatory clarity and flexibility.⁶¹

- Democratically Deficient: Argentina is often described as ‘hyper-presidential’ because of the Constitutional emphasis on the President’s superiority and his practical capability, through decrees and vetoes, to exercise legislative authority in a unilateral and discretionary way.⁶² The 1997 Decree is an example of a Presidential exercise of authority; indeed, it is an example of a ‘need-and-urgency’ decree, a form of legislative action introduced in the 1980s and

⁵⁶ Kadereit & Hines, *ibid*; Select Committee, *op. cit.* note 6, at para. 2.13; Shaw, *op. cit.* note 21, p. 37; E. Singer. Turning Stem Cells into Tissues. 2006. Available at http://www.technologyreview.com/printer_friendly_article.aspx?id=16374 [Accessed 29 Sep 2006]; S. Ertelt. MIT Prof: Embryonic Stem Cell Research Nowhere Close to Helping Patients. 2006. Available at <http://www.lifenews.com/printpage.php> [Accessed 12 Oct 2006].

⁵⁷ See Biocrawler, Stem Cell. 2006. Available at http://www.biocrawler.com/encyclopedia/stem_cell [Accessed 12 Oct 2006]; C. Morel et al. Health Innovation Networks to Help Developing Countries Address Neglected Diseases. *Science*. 2005; 309: 401-403. This is in contrast to the dismal state of science funding in 2002, the height of Argentina’s economic crisis: C. Marzuola. Argentina’s Crisis Heralds Time of Torment for Scientists. *Nature*. 2002; 415: 104.

⁵⁸ See Greenwood et al., *op. cit.* note 7, p. 68; H. Pilcher. Bone Marrow Stem Cells Help Mend Broken Hearts. 2004. Available at <http://www.bioedonline.org/news/news.cfm?art=936> [Accessed 30 Oct 2006]; Medical News Today. Stem Cells Implanted in Brain of Patient Who Suffered a Cerebral Infarction. 2005. Available at <http://www.medicalnewstoday.com/medicalnews.php?newsid=25613> [Accessed 3 Oct 2006].

⁵⁹ Greenwood et al., *ibid*, p. 68. Argentina is constitutionally obliged to foster international relationships and pursue international trade opportunities: s. 27, Argentinean Constitution 1853.

⁶⁰ E. DeSilva. Biotechnology: Developing Countries and Globalization. *World J of Micro & Biotech.* 1998; 14: 463-486, claims that the globalisation of biotechnology acknowledges the participation of developing countries in emerging markets of novel bioproducts.

⁶¹ This endeavour comprises one of the “grand challenges” identified by F. Collins et al. A Vision for the Future of Genomics Research: A Blueprint for the Genomic Era. *Nature*. 2003; 422: 835-847.

⁶² M. Llanos. Understanding Presidential Power in Argentina: A Study of the Policy of Privatisation in the 1990s. *J Latin Am Studies*. 2001; 33: 67-99. Indeed, between 1983 and 1995, approximately half of all Argentine legislation originated in the executive: B. Lamounier. Strengthening the Role of Legislatures in Hemispheric Relations. 2002. Available at <http://www.thedialogue.org/publications/2002/fall/legislatures.pdf> [Accessed 23 May 2007].

subsequently validated by the Supreme Court,⁶³ whereby the President identifies an area of emergency or urgency and issues binding legislation thereon with little or no democratic participation or oversight. Although the Legislature has the power to approve or amend decrees, many are met with silence (ie: tacit approval) and, where they are amended, can be returned to their original form via the President's veto power.⁶⁴ Given this environment, and the legislative inactivity which followed the 1997 Decree, it can fairly be characterised as a top-down and not deliberatively conceived instrument.

In short, and on the whole, Argentina's regulatory situation is fairly characterised as unsatisfactory. To its credit, Argentina has recognised this, and has undertaken preliminary steps toward a new state of governance.⁶⁵ One can only hope that it takes this opportunity to develop a morally grounded and more comprehensive regime for SCR which offers those working in this controversial field sound and explicit guidance and a means to test boundaries. Despite the level of SCR activity already underway in Argentina, one might equally hope that stakeholders will seriously consider the social implications of such cost-intensive research (resulting in cost-intensive treatments) given Argentina's economic inequity and healthcare fragility.⁶⁶ Of course, given the government's multiple roles, including strengthening and modernising the economy and closing the developing/developed divide so that the welfare of all Argentineans is improved, this latter concern may not loom large in the stakeholders' minds.

CONCLUSION

Stakeholders are confronted by a society that is increasingly complex and confusing (characterised, as it is, by rising populations, greater interconnectedness, and an increasing number and scope of human activities). Examples of this abound, but a

⁶³ *Peralta v. Estado Nacional*, (1991) 141 El Derecho 519-548 (SCA). This was the most controversial in a series of Supreme Court cases which extended the President's tenuous and previously rarely used power of rule by decree. For a discussion of this and other cases and the 'creep' of the President's legislative power, see C. Larkins. The Judiciary and Delegative Democracy in Argentina. *Comparative Politics*. 1998; 30: 423-442; K. Eaton. The Logic of Congressional Delegation: Explaining Argentine Economic Reform. *Latin Am Res Rev*. 2001; 36: 97-117; R. Chavez. The Evolution of Judicial Autonomy in Argentina: Establishing the Rule of Law in an Ultrapresidential System. *J Latin Am Studies* 2004; 36: 451-478; H. Fix-Zamudio. Emergency Power and Defence of the Constitution. *Mex Law Rev*. 2007; 7: 801-860.

⁶⁴ G. Negretto. Government Capacities and Policy Making by Decree in Latin America: The Cases of Brazil and Argentina. *Comparative Pol Studies*. 2004; 37: 531-562.

⁶⁵ Arzuaga, *op. cit.* note 38; Baranao, *op. cit.* note 44. In April 2004, the Committee of Ethics in Science & Technology urged the government to lift its blanket ban on cloning so as to allow therapeutic cloning, and to rescind its support for the UN Resolution which would ban all forms of cloning: R. Sametband. Argentina Urged to Support 'Therapeutic' Cloning. 2004. Available at <http://www.scidev.net/News/index.cfm?fuseaction=readNews&itemid=1380&language=1> [Accessed 31 Oct 2006].

⁶⁶ For more on the former, see C. Valdovinos. Growth, Inequality and Social Equity in Argentina. *En Breve*. 2005; 82: 1-4; L. Gasparini et al. Argentina: Monitoring Socio-Economic Conditions in Argentina, Chile, Paraguay and Uruguay. 2005. Available at http://www.wds.worldbank.org/external/default/wdscontentserver/wdsp/ib/2005/07/15/000011823_20050715164315/rendered/pdf/329490v10argen1rsion0lcshd01public1.pdf [Accessed 15 Feb 2007]. For more on the state of healthcare, see J. Uribe & N. Schwab. The Argentine Health Sector in the Context of the Crisis. 2002. Available at [http://wbln0018.worldbank.org/lac/lacinfoclient.nsf/d29684951174975c85256735007fef12/3d29a0ed02294a8b85256db10058dbdd/\\$file/argentinapabp6.pdf](http://wbln0018.worldbank.org/lac/lacinfoclient.nsf/d29684951174975c85256735007fef12/3d29a0ed02294a8b85256db10058dbdd/$file/argentinapabp6.pdf) [Accessed 15 Feb 2007].

particularly relevant one given the present context is the biomedicalisation of society. Under this process, aspects of life previously outside the jurisdiction of medicine are increasingly viewed as medical problems. This social transformation is facilitated by new biotechnologies, which are transforming diagnostic and treatment options.⁶⁷ A consequence of this social complexity and the (new) moral pluralism that it engenders is that the law must regulate relations and activities that were previously unregulated or regulated solely by adherence to (agreed) moral practices; the law is called upon to perform more contested and burdensome functions in the governance of society.

One activity that the law is being called upon to respond to is that of biotech innovation and, more particularly, SCR, which is shaped by two core phenomena that make voluntary reliance on personal morality inadequate, namely disease and commercialisation:

- Disease: Chronic, degenerative and acute diseases visit massive economic and psychological costs on societies, both developed and developing; in many cases, mortality rates are climbing and quality of life (and care) are dropping. Moreover, these diseases increasingly transcend national boundaries (eg: HIV, SARS, Avian Flu). In such a setting, stakeholders (governments, commercial enterprises, healthcarers, patients groups) are turning to innovative avenues of health research like SCR to provide new, novel and cost-effective means of treating disease. As activities increase, actor pools expand, and capabilities improve, clear and comprehensive regulation becomes more important.
- Commercialisation: The direction of biotech and genomic innovation/evolution is driven in large part by corporate agendas, themselves influenced by what is perceived to be most lucrative in global markets.⁶⁸ Contributing to this phenomenon is the fact that academic institution and private company relationships are both increasing and being strengthened.⁶⁹ In consequence, healthcare research (and SCR) regulation is becoming an important mechanism of corporate conduct / business practice regulation, as well as an important element of delivering useful healthcare.

Given the above, and the fact that SCR is an increasingly prevalent and deeply divisive aspect of a quickly evolving social setting, and moreover it is one which incites (often polemical) intercourses amongst publics, decisive legal action preceded by adequate engagement exercises is essential. Whole new subject-specific regimes are not always necessary, but a regime which considers all of the most important elements of the issue and offers a (reasonably) holistic and consistent response is warranted. In the present case, that means regulation which:

⁶⁷ For an exposition of this concept, see A. Clarke et al. Biomedicalization: Technoscientific Transformations of Health, Illness and US Biomedicine. *Am Soc Rev.* 2003; 68: 161-194, who argue that biomedicalisation contributes to and is manifested by (1) the politico-economic constitution of corporatised research, (2) the social emphasis on health risk and the means to monitor same, (3) the increasingly technoscientific nature medical practices, (4) the transformation of biomedical knowledge/information production, management, distribution and utilisation, and (5) the transformation of the human bodies and identities according to biotech understandings.

⁶⁸ K. Rajan. Subjects of Speculation: Emergent Life Sciences and Market Logics in the United States and India. *Am Anthropologist.* 2005; 107: 19-30.

⁶⁹ H. Moses et al. Collaborating with Industry – Choices for the Academic Medical Centre. *New Eng J Med.* 2002; 347: 1371-1375.

- identifies the forms of health research society considers both acceptable and urgent;
- structures the pursuit and influences the direction of that research to facilitate socially acceptable outputs (eg: addresses issues such as sourcing, storing and utilising SCs, and cloning human embryos for research purposes); and
- articulates the limits of health research and research outputs so that they are timely and socially useful (eg: directly and through research commercialisation policies and product and process licensing practices).

Such a regime has the potential to foster innovation while at the same time assuaging our worst fears of misconduct and misapplication.